

Amendments to the Specification:

Please replace the paragraph beginning at page 2, line 17, with the following amended paragraph:

U.S. Patent No. 6,261,519 describes a diagnostic device for measuring the concentration of an analyte in a sample. The device comprises a sample port at one end for introducing a sample. The device also comprises a bladder at the other end that must be depressed, inserted into a liquid sample and released to draw a sample. The device described in U.S. Patent No. 6,261,519 does not further draw the sample passed past a test site to clear the test site so that diffraction or non-diffraction at the test site can be determined.

Please replace the paragraph beginning at page 10, line 4, with the following amended paragraph:

Figure 2, is left side view of device 100. Figure 3, is a cross-sectional view of device 100 taken through line 3-3 of Figure 2. In this illustrated embodiment, the device 100 is sealingly attached to a removable test strip 40 to form a chamber 30 into which a sample can be directed so that sample may contact test strip 40 and test surface 42. The housing 100 further comprises an opening 22 for receiving a sample and a channel 24 connecting the opening 22 to chamber 30 so that sample may be directed from opening 22 to chamber 30. In another embodiment, the opening 22 may further comprise a collection pad onto which a sample may be placed or otherwise deposited for testing. For example, an individual may contact a freshly lanced finger or other body part to the collection pad to deposit a blood sample for testing within the device 100. The collection pad and opening 22 are in fluid communication and connected to chamber 30 via channel 24. The sample can be directed from the opening 22 to test surface ~~[[44]]~~ 42 by operating the means for inducing a pressure differential on a sample to direct the sample to a test surface. The means for inducing a pressure differential on a sample to direct the sample to a test surface may be any means that can be used to direct, force, urge or otherwise compel a sample from one location to another location.

Please replace the paragraph beginning at page 11, line 18, with the following amended paragraph:

A health-care professional or a non-professional may use the following described version of the illustrated device to detect CRP in blood and determine if a person from whom a blood sample, or possibly another type of sample, is obtained is suffering from a bacterial infection. With the handle 54 in the unextended position illustrated in Figure 1, a volume of blood, for example a drop of blood, is contacted to the collection pad and opening 22. Once the sample has contacted the collection pad, handle 54 may be extended to Position 1 as illustrated in Figure 5. The volume of blood is then drawn from the collection pad, through opening 22 and into channel 24 by the vacuum created when handle 54 is moved from a closed position to Position 1. In Figure 5, the sample

60 is illustrated entering optional chamber 34. Optional chambers may be included to provide for various functions. For example, chamber 34 may be provided in the device to include a filter for removing one or more undesirable components from a sample, a diluent to lower the viscosity of and thus increase the flow of a sample through the device, or to contain a reactant, an additive or other useful composition. In a desired embodiment, the diagnostic device includes a means for diluting a sample, for example a diluent, in chamber 34. In this desired embodiment, chamber 34 may contain a diluent or any other composition that may be used to dilute, dissolve or otherwise react with one or more components in a sample or to perform another desirable function on a sample so that the sample is affected in some manner that provides more reliable test results for the analyte being tested. Sample 60 contacts the means for diluting a sample [[34]] via channel 24 when handle 54 is extended to Position 1.

Please replace the paragraph beginning at page 12, line 6, with the following amended paragraph:

The device may be further provided with yet another optional chamber 36. Chamber 36 may be provided in the device to include a filter for removing one or more undesirable components from a sample, a diluent to lower the viscosity of and thus increase the flow of a sample through the device, or to contain a reactant, an additive or other useful composition. In a further desirable embodiment, the diagnostic device includes a means for separating one or more components from a sample in chamber 36. Examples of means for separating one or more components from a sample include a membrane, filter media, porous films, nonwoven films, paper, etc. Such means for separating one or more components from a sample may be used to remove one or more components from a sample that are undesirable or that may adversely affect testing. For example, it may be desirable to remove red blood cells from a blood sample via filtration, lysing or agglutination. Removal of red blood cells from a sample may improve the function of diagnostic devices and methods because red blood cells may interfere with the analyte binding or otherwise associate with the printed binder; thus, removal could improve test accuracy. The means for separating one or more components from a sample may be general and remove a component or components based on a particular property, for example, size or molecular weight. Or, the means for separating one or more components from a sample may be specific to a particular component, for example a bilirubin-binding layer may be included to remove bilirubin. Sample is further directed through channel 24 and into chamber 36 by extending handle 54 to Position 2. Position 2 is illustrated in Figure 6. In Position 2, the sample is illustrated as contacting the test surface [[44]] 42. However, the number of positions may vary and the location of the sample within the device may vary. Once the sample has contacted the test surface [[44]] 42, handle 54 can be further extended, preferably fully extended, to remove excess sample from the test surface so that the test surface can be read. Advantageously, if the volume of chamber is greater than the volume of blood that is produced from a freshly lanced finger (approximately 25 μ L) or greater than the average volume (for example greater than 50 μ L or even greater than 100 μ L)) the liquid sample can be safely stored before the test strip 40 is removed from the device

100. In a desirable embodiment, test strip 40 is removably attached to the device 10 and can be snapped off of or otherwise removed from the device to be viewed or placed in an analyzer for viewing or interpreting the results.

Please replace the paragraph beginning at page 13, line 5, with the following amended paragraph:

In another desirable embodiment, the device is provided with windows and/or indicia, for example numbered windows 1, 2 and 3 illustrated in Figure 8, to assist a user in operating the device. After placing a sample on the touch pad 22, the user pulls handle 54 and aligns piston 52 with Position 1 to pull a sample from the touch pad through channel 24 and into the chamber 34, which includes a means for diluting a sample [[34]]. Position 1 is illustrated in Figure 5 and the sample is illustrated as dashed area. The sample may then be allowed to dilute, dissolve or otherwise react with a desired composition in the chamber for a particular period of time. The device may contact one or more compositions in chamber 34 that can be used to modify the sample in some manner. For example, a composition may be provided to reduce the viscosity of the sample, dissolve solids in the sample, or add reactants or diffraction enhancing elements to the sample. Next, the user further pulls handle 54 to align piston 52 with Position 2 to draw the sample further through channel 24, through the chamber 36, which includes a means for separating [[36]] and into chamber 30. Position 2 is illustrated in Figure 6. In this described embodiment, the sample has been dissolved in a diluent and one or more desirable components have been removed from the sample before the sample contacts the binder-printed test surface 44. Next, the user further pulls handle [[24]] 54 to Position 3 to remove excess sample from the test surface. Position 3 is illustrated in Figure 7. The test strip 40 may now be removed from the device 100 and observed or inserted into a reader to be interpreted.

Please replace the paragraph beginning at page 13, line 26, with the following amended paragraph:

Although Figures 1-10 illustrate a syringe-like device 50 as a means for inducing a pressure differential on a sample, one skilled in the art could configure and construct a device that comprises a means for inducing a pressure differential on a sample that is not a syringe or a syringe-like device. Furthermore, one skilled in the art will appreciate that the devices of the present invention may be configured and constructed to comprise a means for inducing a pressure differential on a sample that uses a positive pressure differential instead of a negative pressure differential to push rather than pull a sample to the test surface. Examples of means for inducing a positive pressure differential include a pump, a plunger, a piston as well as a syringe. The means for inducing a pressure differential may be used to either pull a sample from an opening 22 to a test surface [[44]] 42 or to push a sample from an opening 22 to a test surface [[44]] 42 as long as the means directs a sample or a portion of a sample to the test surface so that the sample can be analyzed.